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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PAKIST03139	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2003/001427	International filing date (day/month/year) 18 JULY 2003 (18.07.2003)	Priority date (day/month/year) 20 JULY 2002 (20.07.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 31/337		
Applicant KOREA INSTITUTE OF SCIENCE AND TECHNOLOGY et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 15 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 19 FEBRUARY 2004 (19.02.2004)	Date of completion of this report 16 NOVEMBER 2004 (16.11.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, Jae Jeong Telephone No. 82-42-481-5604 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/001427

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed☒ the description:

pages 1 - 36

pages _____, as originally filed

pages _____, filed with the demand

☒ the claims:

pages _____

pages _____, as originally filed

pages _____, as amended (together with any statement) under Article 19

pages 37 - 51, filed with the demand

pages _____, filed with the letter of 23/09/2004

☒ the drawings:

pages 1/3 - 3/3

pages _____, as originally filed

pages _____, filed with the demand

☐ the sequence listing part of the description:

pages _____

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☒ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☐ the description, pages _____☒ the claims, Nos. 2 - 4, 34 - 36☐ the drawings, sheets _____5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No. .

PCT/KR2003/001427

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1, 5 - 33, 37 - 73	YES
	Claims		NO
Inventive step (IS)	Claims	1, 5 - 33, 37 - 73	YES
	Claims		NO
Industrial applicability (IA)	Claims	1, 5 - 33, 37 - 73	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: WO 0213815 A1 (Hanmi Pharm. Co.) 21 February 2002

D2: WO 0168139 A1 (Korea Institute of Science and Technology) 20 September 2001

D3: WO 0101960 A1 (Lipocine Inc.) 11 January 2001

The amended (23 Sep. 2004) claims 1, 5 - 32, 72, 73 of the present invention relate to a composition for solubilization of paclitaxel comprising monoolein and oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil). And the amended (23 Sep. 2004) claims 33, 37 - 71 of the present invention relate to a composition for solubilization of paclitaxel comprising monoolein, oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil) and emulsifier.

D1 discloses a composition comprising a drug which is not readily absorbed in the digestive tract (for example, paclitaxel etc.), a compound of formula(I), surfactant (for example, monoglycerides etc.) and oil. D2 concerns a solubilizing composition comprising monoglyceride compound (for example, monoolein etc.), emulsifier, water-insoluble material (for example, paclitaxel etc.) and organic solvent. D3 describes a pharmaceutical composition comprising a triglyceride, a carrier comprising at least two surfactants and a therapeutic agent (for example, paclitaxel etc.).

Although D1-D3 teach the process for preparing and using various types of compositions comprising a paclitaxel, D1-D3 do not disclose the features of the subject matter of claims 1, 5 - 33, 37 - 73, which meet the criteria set forth in PCT Article 33(2), (3) and (4). The composition for solubilization of 0.01 - 20 % by weight of paclitaxel (including emulsifier) comprising 4 - 90 % by weight of monoolein and 0.01 - 90 % by weight of oil (which is selected from a group of triglyceride, iodized oil, vegetable oil and animal oil) is not anticipated by any of the references on record. Thus, the invention described in the present application is considered to be new, inventive and industrially applicable.